No. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS, INC. IN SUPPORT OF THE PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

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INTEREST OF THE AMICUS CURIAE

Intellectual Property Owners, Inc. ("IPO") files this *amicus curiae* brief in support of petitioner Eli Lilly and Company on the writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered March 29, 1989.

IPO was founded in 1972 by a group of individuals who were concerned about the lack of understanding of intellectual property rights in the United States. Members include nearly one hundred large and medium size com-

panies and some smaller businesses and independent inventors who own patents and other intellectual property rights. Members of IPO's Board of Directors are listed in the appendix to this brief. IPO is a nonprofit association exempt from federal income tax under Internal Revenue Code § 501(c)(6).

IPO conducts a government relations program in Washington, D.C. IPO supports legislation to strengthen protection available under the U.S. patent, trademark, copyright, and trade secret laws. Enactment of such legislation helps IPO's members and strengthens incentives for innovation and investment in the United States, improving the country's industrial competitiveness.

The Court of Appeals decision, by expanding the patent infringement exemption of 35 U.S.C. 271(e)(1) beyond drugs and veterinary biological products, may well erode patent rights not only in the area of medical devices, which is the area of the petitioner's patents, but also in the areas of food additives, color additives, agricultural chemicals, and other drug and nondrug products that are subject to regulation by the federal government or may be subject to federal regulation in the future.

This would weaken U.S. patent protection for IPO members, contrary to IPO's commitment to advocating strong rights in patents. IPO seeks to safeguard the full measure of the patent system that gives vital incentives for technological innovation, creativity, and business investment.

SUMMARY OF ARGUMENT

The language of § 271(e)(1) is not ambiguous. The only reasonable construction is that when Congress said it was providing an exemption for "a patented invention . . . for uses . . . under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products", Congress meant patented inventions on drugs or veterinary biological products.

Assuming *arguendo* that there is ambiguity in the language of § 271(e)(1), the analysis of the legislative history by the District Court is persuasive. The Court of Appeals misinterpreted what Congress intended when Congress overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*

Congress did not intend to overrule the *Roche* interpretation of 35 U.S.C. § 271(a) with respect to all types of patented inventions. The 1984 enactment of § 271(e)(1) and the 1988 amendment made exceptions to the overruling of *Roche* even for drugs and veterinary biological products. Congress did not overrule the *Roche* interpretation of § 271(a) with respect to agricultural chemicals regulated by the Environmental Protection Agency. Congress changed the impact of the *Roche* interpretation of § 271(a) only for drugs and veterinary biological products.

ARGUMENT

I. THE COURT OF APPEALS MISINTERPRETED WHAT CONGRESS INTENDED WHEN CONGRESS OVERRULED *ROCHE PRODUCTS, INC. v. BOLAR PHARMACEUTICAL CO.*

The Court of Appeals adopted an extraordinary interpretation of how Congress intended to alter the impact of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[1] when Congress enacted § 271(e)(1). The Court of Appeals was incorrect in its holding that the infringement exemption of § 271(e)(1) applies to medical devices,[2] and the court's opinion stated an incorrect rationale that is broader than the holding.

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[1] 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

[2] Pet. App. 3a. "Pet. App. 3a" refers to page 3a of the appendix to Lilly's petition for certiorari. IPO will refer to the appendix to the petition for certiorari on other occasions using this citation form.

The Court of Appeals viewed the issue as ". . . whether section 271(e)(1) is a limited exception, which applies only to drugs as the district court ruled, or applies generally to patented inventions. . .".[3] According to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all of its ramifications".[4] The Court of Appeals said Congress meant to allow a party to "make, use or sell *any type* of 'patented invention' ", if for "the restricted uses stated therein".[5]

This reasoning is in error. Congress certainly did not intend to overrule the *Roche* interpretation of § 271(a) with respect to "any type" of patented invention. We are not aware of anyone proposing to Congress in 1984 that the *Roche* interpretation of § 271(a) should be amended to such an extent.

Section 271(e)(1) does not even cover all types of drugs and veterinary biological products. The 1984 version of § 271(e)(1) stated that it did not extend to an "animal drug or veterinary biological product". The 1988 amendment to § 271(e)(1), which extended coverage to certain veterinary biological products, excluded biotechnology-related animal drugs and veterinary biological products.

When § 271(e)(1) was enacted, Congress also had before it somewhat similar proposals affecting patent rights in agricultural chemicals regulated by the Environmental Protection Agency.[6] Congress did not enact those pro-

[3] Pet. App. 5a.

[4] Pet. App. 7a.

[5] Pet. App. 7a (emphasis in original).

[6] *E.g.*, H.R. 5529, 98th Cong., 2d Sess. Congress subsequently has considered several other bills affecting patent rights in agricultural chemicals. Some of these bills have proposed to amend § 271(e) to extend it to agricultural chemicals. *E.g.*, S. 1516, 100th Cong., 1st Sess., § 2402, p. 167 (amendment to 35 U.S.C. § 271(e) covering pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act).

posals. Neither petitioner nor respondent advocates that § 271(e)(1) overruled the *Roche* interpretation of § 271(a) as it affects agricultural chemicals.[7]

IPO agrees that the 1984 law did not cover any products regulated by agencies other than FDA.[8] IPO notes, however, that the Court of Appeals opinion can be read to extend the reach of § 271(e)(1) to agricultural chemicals and all other types of patented inventions regulated by *any* federal agency.

The language in § 271(e)(1) does not limit the section to FDA-regulated inventions. It covers ". . . uses reasonably related to the development and submission of information under *a Federal law* which regulates the manufacture, use, or sale of drugs or veterinary biological products" (emphasis added). If one refuses to accept the words "drugs or veterinary biological products" at the end of § 271(e)(1) as being limiting, as did the Court of Appeals, then the section arguably covers all federally regulated, patented inventions.

IPO points to the overbroad language in the opinion of the Court of Appeals only to illustrate that the opinion

[7] Memorandum of Respondent Medtronic, Inc. in Opposition to the Motion of Intellectual Property Owners, Inc. for Leave to File Brief Amicus Curiae in Support of the Petition for Certiorari 2-3; *see* Petition for Writ of Certiorari n.12. The petitioner presents the question for review by this Court as whether the Court of Appeals has expanded the patent infringement exemption to all FDA-regulated products. Petition for Writ of Certiorari at i. The respondent contends the phrase "patented invention" in § 271(e)(1) covers drugs and "medical devices regulated by the Federal Food, Drug and Cosmetics Act. . .". See Respondent's Brief in Opposition to Petition for Writ of Certiorari at i.

[8] The 1988 amendment of § 271(e)(1), expanding the section to cover certain veterinary biological products, includes subject matter regulated by the Secretary of Agriculture under the Virus-Serum-Toxin Act. *See* Pub. L. No. 100-670, Title II, "Patent Terms". Thus, § 271(e)(1) now covers some subject matter not regulated by FDA.

makes incorrect assumptions about §§ 271(a) and 271 (e)(1). These assumptions were the foundation for the court's opinion.

Circuit Judge Newman dissenting from the denial of a rehearing *en banc*,[9] argued that the Court of Appeals was legislating. Judge Newman observed that Congress, not the court, is empowered to legislate in matters affecting patent rights. Newman dissent, Pet. App. 13a, citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567 (1886).

II. THE PLAIN LANGUAGE OF THE STATUTE AND THE LEGISLATIVE HISTORY SHOW THE PATENT INFRINGEMENT EXEMPTION OF § 271(e)(1) IS LIMITED TO DRUGS AND VETERINARY BIOLOGICAL PRODUCTS

The Court of Appeals concluded that "ambiguous language" in the statute and "ambiguous statements in the legislative history" supported inclusion of at least medical devices, food additives, and color additives within the infringement exemption of 35 U.S.C. § 271(e)(1), in addition to drugs and veterinary biological products.[10] As explained above, IPO believes the Court of Appeals opinion possibly extends even beyond FDA-regulated products, to agricultural chemicals.

IPO submits, however, that the plain language of the statute and the legislative history show the patent infringement exemption for drugs and veterinary biological products in § 271(e)(1) does not extend to medical devices or to any other type of patented invention.

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[9] Pet. App. 10a.

[10] *See* footnote 5 of the Court's opinion, Pet. App. 5a. There are reasons for distinguishing between drugs and non-drug, FDA-regulated products. Lilly's petition for Certiorari sets forth the reasons, and they will not be repeated here. *See* Petition for Writ of Certiorari 14-18.

The opinion by the Court of Appeals did not analyze the arguments considered by the District Court. Judge Newman's dissent highlights the incomplete nature of the analysis by the Court of Appeals. Judge Newman summarized the District Court opinion as follows:

> The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set forth in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs.

Pet. App. 11a.

The only reasonable construction of § 271(e)(1) is that when Congress said it was providing an exemption for "a patented invention . . . for uses . . . under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products", Congress meant patented inventions on drugs or veterinary biological products. The language is not ambiguous.

The respondent argues that "patented invention" means any type of invention that happens to be regulated under the same federal law that regulates drugs or veterinary biological products. This is a very strained construction. If airplanes and automobiles were regulated under the same federal law, Congress would not exempt airplane inventions merely by referring to all patented inventions falling under the law regulating automobiles.

Assuming *arguendo* that there is ambiguity in the language of § 271(e)(1), IPO submits that the analysis of

the legislative history by the District Court [11] is persuasive. The House Committee Report states several times that the purpose of § 271(e)(1) was to allow testing of generic drugs before the date of expiration of the patent.[12] The terminology used in the Federal Food, Drug and Cosmetic Act also supports the interpretation that when Congress said drugs and veterinary biological products, Congress meant drugs and veterinary biological products.

CONCLUSION

IPO urges the Court to reverse the ruling by the Court of Appeals for the Federal Circuit that the infringement exemption of § 271(e)(1) covers other patented inventions besides drugs and veterinary biological products.

Respectfully submitted,

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November 24, 1989

[11] Pet. App. 19a.

[12] H.R. Rep. No. 857, 98th Cong., 2d Sess., pts. 1 & 2 (1984).

APPENDIX

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